

21



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,646	03/20/2002	Jan Van Der Greef	101137-31	6797

27387 7590 12/15/2004

NORRIS, MCLAUGHLIN & MARCUS, P.A.
875 THIRD AVE
18TH FLOOR
NEW YORK, NY 10022

EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
----------	--------------

1641

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,646

Applicant(s)

GREEF ET AL.

Examiner

Deborah A Davis

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 21, 2004 has been entered. Currently, Claims 1-11 are pending and under consideration.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Nedved et al (Characterization of Benzodiazepine "Combinatorial" Chemical Libraries by On-Line Immunoaffinity Extraction, Coupled Column HPLC-Ion Spray Mass Spectrometry – Tandem Mass Spectrometry, Analytical Chemistry, 1996, Vol. 68, pages 4228-4236).

Nedved et al anticipates the instant claims by teaching on-line detection methods comprising immunoaffinity extraction of analytes using reversed-phase HPLC columns

Art Unit: 1641

coupled to a mass spectrometer (see abstract). Claim 1 is directed to adding a controlled amount of affinity molecule to an effluent followed by a separation step using a restricted-access support (see abstract). Nedved et al teaches antibodies to benzodiazepine were used to screen library components and were added to a Protein G column (effluent) wherein a pH change in the mobile phase eluted the benzodiazepine-antibody complexes on to a restricted access media column (support) thereby separating the selected benzodiazepine from the antibody (see abstract). The instant claim 1 also discloses a second step of separation whereby the analyte-affinity molecule complex is permeated flowed by a step to dissociate the analyte-affinity molecule complex followed by detection of the analyte using mass spectrometer. Nedved et al teaches a second step of backflushing the restricted access column (support) wherein the dissociated benzodiazepines analyte is eluted onto an analytical reversed phase column for separation and detection and characterization using mass spectrometry (see abstract and page 4229, column 2, paragraph 4). Claim 2 is directed to the use of a restricted access support in which the affinity molecule is retained followed by elution of the analyte to be detected by mass spectrometry. Nedved et al teaches a second separation step using restricted access column (support) wherein the antibody was retained after elution of the benzodiazepines analyte (page 4230, column 1 paragraph 1). Acetic acid was used to dissociate analytes with a pH of 7.4 as recited in claim 4 (page 4229, column 2, paragraphs 1-2 and page 4231 column 2, paragraph 1). The fractionation step used to separate the analytes were HPLC and other chemical combinatorial chemistry library systems as recited in claims 5 and 6 (see abstract and

page 4229, column 1, paragraphs 1-2). Nedved et al discloses different instrumentation of mass spectrometer used in the detection of analytes such as MS/MS, tandem mass spectrometry and on line ion spray spectrometry as recited in claim 7 (page 4228, column 2, paragraph 2). The affinity proteins used were monoclonal and polyclonal antibodies to known benzodiazepine compositions as recited in claims 9 and 10. Known and unknown compounds such as pharmaceuticals are detected by utilizing chemical libraries as taught by Nedved et al and as recited in claim 11 (page 4228, column 2, paragraph 1).

Response to Arguments

4. Applicant's arguments filed September 21, 2004 have been fully considered but they are not persuasive:
5. Applicant's argument that the reference of Nedved requires immobilizing antibodies on an insoluble Protein G support to form the affinity complex, whereas applicant's amended claim 1 requires that the affinity molecule-analyte complexes to be formed in a liquid phase and maintains that the difference in forming affinity molecule analyte complexes is sufficient to find the claimed subject matter patentable over the Nedved reference. This argument is noted but not found to be persuasive.

In response to applicant's argument, the amended claim 1 does not differ from the reference of Nedved. Although the affinity complex of Nedved was not formed in the effluent, as was applicant's, the affinity complex was eluted off of the support column into the effluent, which is the liquid phase. Therefore, the affinity complex is in effluent

Art Unit: 1641

before as required by the amended claim 1. It is also noted that Neved et al teaches the steps of immobilization of the antibody and the complex being formed in a solid phase, the claim is drawn to comprising language and therefore does not prohibited the additional steps taught by Neved et al.

Conclusion

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

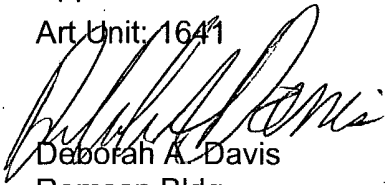
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

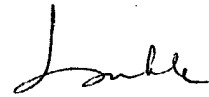
Application/Control Number: 09/980,646

Page 6

Art Unit: 1641



Deborah A. Davis
Remsen Bldg.
Room 3D58
December 3, 2004



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

12/13/04